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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,725	07/21/2003	Bret Benton	0045807-7011663004	8417

23639 7590 06/27/2007
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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/624,725	BENTON ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendments

It is noted that a preliminary amendment to the claims was filed 7/21/03. However, the amendment is both noncompliant with 37 CFR 1.121 and confusing. The amendment does not contain a listing of all the claims, as the amended 37 CFR 1.121 requires, nor containing a marked up version of at least claim 73, as required by 37 CFR 1.121 before the new rule became effective on 7/30/03.

Thus, the amendment has not been entered.

It is also noted that the claim listed between claim 16 and 18 is numbered as "11," Given there is already a claim 11 and the location of the claim, it is considered as claim 17 in the restriction requirement below.

Consequently, only claims 1-30 are pending.

Restriction/Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3 and 8-9, drawn to a method for treating a bacterial infection of a mammal using a compound active against a bacteria gene selected from SEQ ID NOS 1-105, classified in class 514, subclass 183.

II. Claims 4-7, drawn to a method for treating a bacterial infection of a mammal using an antibacterial agent that specifically inhibits a biochemical pathway requiring the

expression product of a gene selected from SEQ ID NOS 1-105, classified in class 514, subclass 2.

III. Claims 10-13, drawn to a method for screening for an antibacterial agent active on the gene SEQ ID NOS 1-105, classified in class 435, subclass 6.

IV. Claim 14, drawn to a method for evaluating an agent active on a gene selected from SEQ ID NOS 1-105, classified in class 435, subclass 6.

V. Claims 15-16, drawn to a method for diagnosing the presence of bacterial strain having a gene selected from SEQ ID NOS 1-105, classified in class 435, subclass 5.

VI. Claims 17-18, drawn to a pharmaceutical composition comprising a compound active on a gene selected from SEQ ID NOS 1-105, classified in class 435, subclass 6.

VII. Claim 19, drawn to a method for making an antibacterial agent active on a gene selected from SEQ ID NOS 1-105, classified in class 435, subclass 6.

VIII. Claim 20, drawn to a novel antibacterial compound active against a gene selected from SEQ ID NOS 1-105, classified in class 435, subclass 6.

IX. Claim 21, drawn to a purified bacterial strain expressing a mutated gene selected from SEQ ID NOS 1-105, classified in class 435, subclass 6.

X. Claims 22-28, drawn to a nucleic acid, vector or cells comprising same having a gene selected from SEQ ID NOS 1-105, classified in class 536, subclass 23.1.

XI. Claims 29-30, drawn to a polypeptide encoded by a gene selected from SEQ ID NOS 1-105, classified in Class 530, subclass 300.

The inventions of groups I-XI are independent/distinct, each from the other because of the following reasons:

The inventions of groups I-V and VII, are directed to related processes, each from another. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of the groups are related because they are all related to a gene selected from SEQ ID NOS 1-105, and related antibacterial. However they are distinct because they comprise distinct steps and produce different results. Group I involves treating a bacterial infection of a mammal, comprising administering to a mammal suffering from a bacterial infection an amount of a compound active against a bacterial gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105 sufficient to inhibit the growth of bacteria involved in said infection. Group II involves treating a bacterial infection in a mammal comprising administering to said mammal an amount of an antibacterial agent effective to reduce said infection, wherein said antibacterial agent specifically inhibits a biochemical pathway requiring the expression product of a gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105, and wherein inhibition of said biochemical pathway inhibits the growth of said bacterium in vivo. Group III involves screening for an antibacterial agent, comprising determining whether a test compound is active against a bacterial gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105. Group IV involves screening for an antibacterial agent, comprising the steps of: a) contacting a cell expressing a polypeptide encoded by a gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105 with a test

compound; and b) determining whether the amount or level of activity of said polypeptide is altered; wherein an alteration in said amount or level of activity of said polypeptide is indicative of a useful antibacterial agent. Group V involves screening for an antibacterial agent, comprising the steps of: a) contacting a polypeptide or a biologically active fragment thereof with a test compound, wherein said polypeptide is encoded by a gene selected from a group consisting of the genes corresponding to SEQ ID NO. 1-105; and b) determining whether said test compound binds to said polypeptide or said fragment; wherein binding of said test compound to said polypeptide or said fragment is indicative of a useful antibacterial agent. And group VII involves diagnosing the presence of a bacterial strain having a gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105, comprising probing with an oligonucleotide at least 15 nucleotides in length which specifically hybridizes to a nucleotide sequence which is the same as or complementary to a portion of the sequence of a bacterial gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105. Clearly the methods are mutually exclusive, not obvious variants and have different modes of actions, functions and effects.

The inventions of groups VI and VIII-XI are directed to related products, each from another. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products of the groups are related because they are all related to a gene selected from SEQ ID NOS 1-105, and related to antibacterial activity. However they are distinct. Group VI involves a

pharmaceutical composition comprising a pharmaceutically acceptable carrier and a compound active on a bacterial gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105. Group VIII involves a novel compound having antibacterial activity, wherein said antibacterial activity is against a bacterial gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105 or a product thereof. Group IX involves a purified bacterial strain expressing a mutated gene selected from the group consisting of the genes corresponding to SEQ ID NO. 1-105, wherein said mutated gene confers a growth conditional phenotype. Group X involves nucleic acids of SEQ ID NO. 1-105, and group XI involves a polypeptide encoded by a gene from SEQ ID NO. 1-105. Clearly the products are not obvious variants and have different modes of actions, functions and effects.

Any one of the inventions of groups I-V and VII and any of the inventions of groups VI and VIII-XI are related as product and distinct processes of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product ms claimed can be used in a materially different process of using that product (M.P.E.P. j 806.05(h)). In the instant case each of the distinct products of groups VI and VIII-XI can be used in the processes of groups I-V and VII, which are distinct for reasons set forth above.

Sequence Election Requirement Applicable to All Groups

In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants

must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D., can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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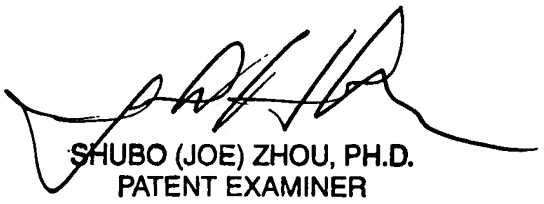

SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER